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HC

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| 097036,819      | 03/09/98    | SHAMI A              | 107-1450-C          |

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EXAMINER  
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|                  |              |
|------------------|--------------|
| ART UNIT<br>1641 | PAPER NUMBER |
|------------------|--------------|

DATE MAILED: 06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/036,819

Applicant(s)

El Shami

Examiner

S. Devi, Ph.D.

Group Art Unit

1641



☒ Responsive to communication(s) filed on Apr 12, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 41-52 ~~is~~are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 28-40 ~~is~~are ~~cancelled~~ cancelled.

☒ Claim(s) 41-52 ~~is~~are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### **DETAILED ACTION**

1) Acknowledgment is made of Applicant's amendment filed 04/12/99 (paper no. 5) in response to the Office Action mailed 02/04/99 (paper no. 4). With this, Applicants have amended the specification.

### **Claims Status**

2) Claims 28-40 have been canceled via paper no. 5.  
New claims 41-52 have been added via paper no. 5.  
Claims 41-52 are pending in the instant application and 33-40 are under examination.

### **Prior Citation of Title 35 Sections**

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Continuity Status**

5) Acknowledgment is made of Applicant's amendment to the first paragraph of the specification to reflect the continuity status of the instant application.

### **Objection Withdrawn**

6) The objection to the specification made in paragraph 5(a) of the Office Action mailed 02/04/99 (paper no. 4) is withdrawn in light of Applicants' amendment to the specification.

### **Objections Maintained**

7) The objection to the informal drawings made in paragraph 6 of the Office Action mailed 11/12/98 (paper no. 8) under 37 C.F.R. 1.84 is maintained for reasons set forth therein. Applicant requests that the submission of new formal drawings be held in abeyance pending allowance.

8) The objection to the specification made in paragraph 5(b) of the Office Action mailed 02/04/99 (paper no. 4) is maintained for reasons set forth therein. Although Applicants have replaced Tables 20-25 via paper no. 5, the rest of the Tables and related text have not been

amended. However, Applicant assures the Office that the latter will be deleted upon indication of allowance.

9) The objection to the specification made in paragraph 5(c) of the Office Action mailed 02/04/99 (paper no. 4) is maintained for reasons set forth therein. The instant application is submitted with 20 Figures. However, the specification does not include the required section: "Brief Description of the Drawings" to describe these Figures. Further, the specification does not appear to refer to any of the submitted Figures. A reference to brief description of the drawing(s) as set forth in 37 C.F.R 1.74 is required. Correction is required.

#### **Rejections Moot**

10) The rejection of claims 28-40 made in paragraph 6 of the Office Action mailed 02/04/99 (paper no. 4) under 35 U.S.C. §112, second paragraph, as being indefinite is moot in light of Applicant's cancellation of the claims.

11) The new-matter rejection of claims 28 and 29 made in paragraph 7 of the Office Action mailed 02/04/99 (paper no. 4) under 35 U.S.C. §112, first paragraph, is moot in light of Applicant's cancellation of the claims.

12) The rejection of claims 28-40 made in paragraph 10 of the Office Action mailed 02/04/99 (paper no. 4) under 35 U.S.C. §102 and 103, based on public use and sale is moot in light of Applicant's cancellation of the claims.

13) The rejection of claims 28-40 made in paragraph 11 of the Office Action mailed 02/04/99 (paper no. 4) under 35 U.S.C. § 103 as being unpatentable over the lost count of Interference no. 101,933 is moot in light of Applicant's cancellation of the claims.

#### **New Rejections**

14) Applicants are asked to note the new rejections made in this Office Action. Applicants' amendment necessitated the new grounds of rejection presented in this Office Action.

#### **Rejection under 35 U.S.C. 112, First paragraph**

15) Claims 41-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention.

Claim 41 currently includes following newly added limitations as shown below in bold:

41. A method for measuring the concentration of free testosterone ligand in a biological fluid in the presence of bound ligand in a biological fluid in the presence of bound ligand and endogenous binding proteins, without disturbing the equilibrium between said free ligand and protein-bound ligand, which method comprises

(a) incubating, **in the absence of salicylate, 2,4-dinitrophenol and 8-anilino-1-naphthalenesulfonic acid**, a sample of the biological fluid with (i) a ligand analog tracer which, due to its chemical structure, does not bind to some of the endogenous binding proteins **but does bind to at least one other endogenous binding protein**, (ii) a concentration of a specific ligand binder **having an affinity constant and selectivity for the said free ligand such that the equilibrium between free ligand and protein-bound ligand is not disturbed** and (iii) a concentration of a specific inhibitor agent that inhibits the binding of the ligand analog tracer to said at least one other endogenous binding protein **sufficient to block reaction between the ligand analog tracer and said at least one other endogenous binding protein without displacing ligand from protein-bound ligand**;

(b) separating the ligand analog tracer bound to the specific ligand binder from unbound tracer; and

(c) determining the concentration of said free ligand in said biological fluid.

However, there appears to be no support in the instant specification for these added limitations.

Applicant has **not** pointed to the specific parts of the disclosure that support all these newly added limitations or amendments to the claims. With regard to the limitation “in the absence of salicylate, 2,4-dinitrophenol and 8-anilino-1-naphthalenesulfonic acid”, Applicant contends that (see page 7, first paragraph):

The absence of salicylate, 2, 4-dinitrophenol and 8-anilino-1-naphthalenesulfonic acid (ANS) is disclosed at page 26, first full paragraph.

However, this part of the specification does not support the claimed method being carried out “in the absence of salicylate, 2,4-dinitrophenol and 8-anilino-1-naphthalenesulfonic acid”, instead supports the claimed method that can be carried out in the absence of sulfobromophthalein, the specific inhibitor agent recited in part (iii) of claim 41 as shown above. Contrary to what is now claimed, the instant specification has descriptive support for a method of measuring the concentration of free testosterone ligand in a biological sample in presence of blocking agents. For instance, the last two lines on page 24 of the instant specification recite:

Blocking agents were added, as described in the specific examples below.

Therefore, the new limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original

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disclosure, or even omission of a step from a method. See MEP. 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitations, or to remove the new matter from the claim.

#### Remarks

16) Claims 41-52 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

18) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 8.00 a.m. to 4.00 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 1999



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-691